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Not binding precedent

Paper 44

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference No. 105,135

SCRIPPS RESEARCH INSTITUTE
(5,622,931),
Junior Party,

v.

GENENTECH, INC.
(08/437,989 and 08/444,934),
Senior Party.

Entered: 28 February 2005

Decision - Bd. R. 125(a) - Preliminary motions

Before TORCZON, MEDLEY, and POTEATE, Administrative Patent Judges.[1]

TORCZON, Administrative Patent Judge.

INTRODUCTION

This interference is about priority of invention for the soluble portion of human tissue factor [hTF] protein with a specific amino acid sequence. The junior party, Scripps, has filed five motions:

Preliminary motion 1 (Paper 36) for judgment under 35 U.S.C. 135(b) (opposition, Paper 59, and reply, Paper 64);

Preliminary motion 2 (Paper 45) for judgment under 35 U.S.C. 112(1) (opposition, Paper 60, and reply, Paper 65);

[1] As part of Board efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, subsequent papers in this case originating at the Board will not have signatures. The parties have agreed to participate in the electronic filing pilot program, which has its own standard for party signatures.

Preliminary motion 3 (Paper 46) for judgment under 35 U.S.C. 112(1) (opposition, Paper 61, and reply, Paper 66);

Preliminary motion 4 (Paper 47) for judgment under 35 U.S.C. 112(2) (opposition, Paper 62, and reply, Paper 67); and

Preliminary motion 5 (Paper 48) attacking accorded benefit (opposition, Paper 63, and reply, Paper 68).

The senior party, Genentech, has filed two responsive motions:

Preliminary motion 2 (Paper 41) adding claims (opposition, Paper 57, and reply, Paper 72) and

Corrected preliminary motion 3 (Paper 49) adding more claims (opposition, Paper 58, and reply, Paper 71).

FINDINGS OF FACT

The following enumerated findings are supported by at least a preponderance of the evidence. For each motion, the movant bears the ultimate burden of proof for the relief requested. Bd. R. 121(b); Velander v. Garner, 348 F.3d 1359, 1369-70, 68 USPQ2d 1769, 1777 (Fed. Cir. 2003).

The count

[1] The sole count of the interference is (Paper 1, Notice Declaring Interference, at 4):

A composition of claim 1 of the 5,622,931 patent.

[2] Claim 1 of the 931 patent is [3009[2]]:

1. A composition comprising an aqueous solution of human tissue factor heavy chain protein wherein said protein is soluble and has an amino acid residue sequence represented by FIG. **1** from position 1 to position 219.

[3] The amino acid residues of 931 patent FIG. **1** are [3009]:

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[2] Scripps exhibits are numbered from 3001; Genentech exhibits, from 1001.

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                    -30         -20         -10
          ME TPAWPRVPRP ETAVARTLLL GWVFAQVAGA

          10          20          30          40
SGTTNTVAAY NLTWKSTNFK TILEWEPKPV NQVYTVQIST

          50          60          70          80
KSGDWKSKCF YTTDTECDLT DEIVKDVKQT YLARVFSYPA

          90         100         110         120
GNVESTGSAG EPLYENSPEF TPYLETNLGQ PTIQSFEQVG

         130         140         150         160
TKVNVTVEDE RTLVRRNNTF LSLRDVFGKD LIYTLYYWKS

         170         180         190         200
SSSGKKTAKT NTNEFLIDVD KGENYCFSVQ AVIPSRTVNR

         210         220         230         240
KSTDSPVECM GQEKGEFREI FYIIGAVVFV VIILVIILAI

         250         260
SLHKCRKAGV GQSWKENSPL NVS
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The junior party

[4] Scripps is involved in the interference on the basis of a patent (Paper 1 at 2):

> T.S. Edgington & J.H. Morrissey, "Human tissue factor related DNA segments, polypeptides and antibodies", 5,622,931 (issued 22 April 1997).

[5] The 931 patent issued from the 07/880,079 [079] application, filed 29 April 1992.

[6] Scripps was further accorded the benefit (Paper 1 at 3) of:

> 07/165,939 [939] (filed 9 March 1988) (issued as 5,223,427), and
>
> 07/067,103 [103] (filed 25 June 1987) (issued as 5,110,730).

[7] Scripps' 931 patent has two claims (1 and 2), both of which have been designated (Paper 1 at 4) as corresponding to the count.

The senior party

[8] Genentech is involved in the interference on the basis of two applications (Paper 1 at 3):

> R.M. Lawn, G.A. Vehar & K.L. Wion, "Methods and deoxyribonucleic acid for the preparation of tissue factor protein", U.S. Appln. 08/437,989 [989] (filed 10 May 1995) and
>
> R.M. Lawn, G.A. Vehar & K.L. Wion, "Methods and deoxyribonucleic acid for the preparation of tissue factor protein", U.S. Appln. 08/444,934 [934] (filed 22 May 1995).

[9] Genentech was further accorded the benefit (Paper 1 at 3) of:

> 08/167,715 [715] (filed 15 December 1993),
>
> 08/167,785 [785] (filed 15 December 1993),
>
> 07/969,863 [863] (filed 30 October 1992),
>
> 07/620,431 [431] (filed 30 November 1990),
>
> 07/035,409 [409] (filed 7 April 1987), and
>
> 07/013,743 [743] (filed 12 February 1987).

[10] Genentech's 989 application has several claims, only two of which (22 and 39) have been designated as corresponding to the count (Paper 1 at 4).

[11] Genentech's 934 application has twenty-one claims, only sixteen of which (4-6, 8, 20, 21, 23, 27, 28, 31-36 and 41) have been designated as corresponding to the count (Paper 1 at 4).

Scripps preliminary motion 1: judgment under § 135(b) for 934 claims

[12] Scripps moves (Paper 36 at 2) to have all of Genentech's involved 934 application claims held to be unpatentable under the late claiming bar of § 135(b)(1).

Section 135(b) codifies a legal principle akin to laches imposing a statute of repose on interferences so that the patentee might be more secure in his patent rights. In re Berger, 279 F.3d 975, 982, 61 USPQ2d 1523, 1527 (Fed. Cir. 2002). The intent in enacting § 135(b) was to limit the time during which an interference might be provoked. Berman v. Housey, 291 F.3d 1345, 1351, 63 USPQ2d 1023, 1027 (Fed. Cir. 2002).

[13] The involved Scripps 931 patent issued 22 April 1997 (Paper 36, fact 4, admitted in Paper 59).

[14] The critical date for purposes of § 135(b)(1) is one year after the Scripps 931 patent issue date: 22 April 1998.

[15] On 6 December 2002, Genentech filed an amendment to add "fragment" to the involved 934 application claims (Paper 36, fact 5, admitted in Paper 59).

[16] Scripps avers (Paper 36, fact 2, record citation omitted) that "The claims pending in Genentech '934 prior to December 6, 2002 did not include the limitation 'fragment'."

[17] Genentech counters (Paper 59 at 2) that "the word 'fragment' is not limiting."

[18] The 6 December 2002 amendment [3008] of Genentech 934 claim 4 is illustrative of the changes to the claims (brackets indicate deletion; underlining, addition):

> 4. (five times amended) Purified human tissue factor [protein] fragment expressed from a nucleotide molecule encoding a tissue factor selected from the group consisting of tissue factor having an amino acid sequence as provided in Figure 2 from at least amino acid residue one to at least amino acid residue 219, and human tissue factor having an amino acid sequence as provided in Figure 2 from at least amino acid residue one to at least amino acid residue 219 wherein an amino acid residue at an – or O-glycosylation site is substituted, wherein the tissue factor has activity in a clotting assay with human plasma.

[19] Prior to the 6 December 2002 amendment, none of the involved 934 application claims had been allowed (Paper 36, fact 6, admitted in Paper 59).

[20] Scripps contends that the claims were amended to overcome a double-patenting rejection (Paper 36, fact 3).

[21] Genentech counters (Paper 59 at 2) that the amendment was made to "avoid" a double-patenting rejection rather than to "overcome" a rejection that had not been made.

[22] Genentech complains (Paper 59 at 8-9) that Scripps has not argued the limitations of each claim or provided much in the way of specific claim analysis.

[23] Scripps responds (Paper 64 at 5) that Genentech has not contested that its claims are directed to the same or substantially the same invention as Scripps claim 1.

As movant, Scripps bears the ultimate burden of proof for the relief requested in its motion. Bd. R. 121(b); Velander, 348 F.3d at 1369-70, 68 USPQ2d at 1777. We agree with Genentech that Scripps has not argued the basis for unpatentability with specificity for each claim. Scripps focuses on the four independent claims on the theory that the added or substituted language infects all of the dependent claims equally. The premise is false as this case shows. Scripps argues that the unamended claims were too broad to be substantially the same as its invention. Proper dependent claims, however, should be narrower than the independent claims. Hence, a dependent claim might be the basis for overcoming the § 135(b)(1) bar.

We agree with Scripps that Genentech does not contest that its claims are directed to the same or substantially the same invention as Scripps' claim 1. Indeed,

Genentech does not appear to contest the initial "triggering" portion of § 135(b)(1). Instead, Genentech's arguments focus on the second "safe harbor" provision of the statute: whether it had a timely claim to the same invention. Berger, 279 F.3d at 982-83, 61 USPQ2d at 1528. Hence Genentech's focuses on claim 5, which depends from independent claim 4. The safe-harbor test is not an obviousness test; rather the analysis focuses on the interfering claim to determine whether all material limitations of the copied claim "necessarily occur" in a prior claim. Id., 279 F.3d at 982, 61 USPQ2d at 1528.

[24] The independent claims have the following relevant formulations [3008] (brackets showing 2002 deletions, except the "sic" in claim 20; underlinings showing additions):

> 4. Purified human tissue factor [protein] fragment...selected from the group consisting of tissue factor having an amino acid sequence as provided in Figure 2 from at least amino acid residue one to at least amino acid residue 219, and [a glycosylated variant of the same].
>
> 20. A soluble isolated tissue factor fragment...the tissue factor having the amino acid sequence shown in Figure 2 from amino acid one to an amino acid residue between amino acid residues [sic] 219 and amino acid residue 263....
>
> 31. Recombinant human tissue factor [protein] fragment...comprising from amino acid residue one to amino acid residue 219 as provided in Figure 2....
>
> 41. Recombinant human tissue factor [protein] fragment comprising an amino acid sequence from amino acid residue one to amino acid residue 219 as provided in Figure 2....

[25] Other than as shown above, the claims had not been amended since 1997 (Paper 59, fact 9, admitted in Paper 64).

The Board must give a claim its broadest reasonable construction. In re Bigio, 381 F.3d 1320, 1324, 72 USPQ2d 1209, 1210-11 (Fed. Cir. 2004). In claim 4, the use of the transitional phrase "having" could be treated as an "open" transition, but only to the extent the claim as a whole requires an open construction. Crystal Semiconductor Corp. v. TriTech Microelec. Int'l, Inc., 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001). The two "at least" phrases in claim 4 compel a broader reading. Cf. In re Crish, 393 F.3d 1253, 1257, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004) (construing "comprising at least...consists" as open to more than the "consists" alone would suggest). Thus, the broadest reasonable construction of claim 4 would make the substitution of "fragment" for "protein" a material change because the "protein" version was open to the inclusion of the full-length protein in addition to fragments.

Claim 20 includes the relevant limitations "soluble" and "amino acid sequence shown in Figure 2 from amino acid one to an amino acid residue between amino acid residues 219 and amino acid residue 263". The full-length hTF protein is membrane bound rather than soluble in an aqueous medium like serum. Moreover, the full-length protein has residues 1-263, while the claimed polypeptide terminates between 219 and 263. Thus, in claim 20, the addition of "fragment" did not materially affect the scope of the claim since it was already implicitly directed to fragments.

In claim 31, the relevant limitation is "comprising" residues 1-219. This format leaves the claimed hTF open to additional residues, up to and including the 1-263 residues of full-length hTF. Hence, the addition of "fragment" materially changed

claim 31. Claim 41 has an analogous problem with the consequence that substituting "fragment" is again material.

[26] Genentech observes (Paper 59 at 10) that its earlier version of claim 5, which depends from claim 4, excluded the transmembrane portion of hTF, and thus was a fragment of hTF.

[27] Claim 5 [3008 at 2] defines the invention as follows:

> 5. The tissue factor [protein] fragment of claim 4 wherein the nucleotide molecule does not encode the transmembrane domain defined by amino acids 220 to 243 as provided in Figure 2.

Claim 5 thus further limits claim 4 by excluding polypeptides with an intermediate (220-243 of 1-263) range of residues.

[28] The original version of claim 5, filed in 1987, excluded the transmembrane domain (Paper 59, fact 4, admitted in Paper 64).:

> 5. The tissue factor protein of claim 4 wherein the transmembrane domain is deleted.

[29] A pre-December 2002 decision of the Board, Ex parte Lawn, App. No. 2001-0448 (26 July 2002) [1002], construed exclusion of the transmembrane domain to require exclusion of the remainder of the C-terminal[3] portion of hTF--i.e., not just residues 220-243, but residues 244-263 as well--relying on expert declaration testimony for support of the holding that one skilled in the art would have necessarily read the claim narrowly.

Claims must be construed through the eyes of one of ordinary skill at the time of the invention. Multiform Dessicants, Inc. v. Medzam, 133 F.3d 1473, 1477, 45 USPQ2d

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[3] The carboxy terminal, distinct from the N-terminal or amino terminal. Proteins are customarily numbered from the N-terminal to the C-terminal.

1429, 1432 (Fed. Cir. 1998). While neither we nor Scripps are bound by earlier determinations, the Board's holding in Lawn shows that the substitution of "fragment" for "protein" in claim 5 added nothing material to the construction of the claim as it was understood at the time of the amendment.

Since claims 5 and 20 satisfy the safe-harbor provision of § 135(b)(1), and the movant (and the opponent for that matter) did not argue the other claims with specificity, we will not attempt to divine whether the other claims should be held unpatentable.[4] Scripps preliminary motion 1 is DENIED.

Scripps preliminary motion 2: judgment under § 112(1) for 934 claims

[30] Scripps moves (Paper 45 at 2) to have all of Genentech's involved 934 application claims except claims 24 and 25 held to be unpatentable under § 112(1) for lack of written description and enabling support.

Written description

[31] The unpatentability of the claims is not argued separately with specificity, but broadly with groupings corresponding to the four independent claims, and with the argument centering on support for a 1-219 residue fragment (Paper 45).

[32] The relevant portion of Figure 2 in the 934 application relating to residues 1-263 is identical to FIG. 1 of the count (Paper 45, fact 1, admitted in Paper 60).

[33] The 934 application generally refers to variants of hTF, including substitutional, insertional, and deletional variants (Paper 45, fact 3, admitted in Paper 60).

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[4] The failure to brief the other claims fully leaves open the question of whether, given the difference between the anticipation/obviousness test for correspondence of claims to a count and the materiality test for the § 135(b)(1) bar, § 135(b)(1) is moot for obvious variants of a claim falling within the safe harbor.

[34] The 934 application identifies one aspect of the invention as directed to hTF derivatives, in particular derivatives lacking the signal sequence and the hydrophobic or transmembrane portion of the protein near the C-terminal of the protein (Paper 45, fact 4, admitted in Paper 60).

[35] The 934 application provides [1003 at 12:31-13:5]:

> Deletions are characterized by the removal of one or more amino acid residues from the tissue factor protein sequence. Typically, no more than about from 2 to 6 residues are deleted at any one site within the tissue factor protein molecule, although deletion of residues -31 to -1 inclusive will be undertaken to obtain met-tissue factor protein, a variant adapted for intracellular direct expression of met-mature tissue factor protein. Another deletion is of the transmembrane domain located at about residues 220 to 242 of the tissue factor protein molecule.

[36] The 934 application further provides [1003 at 13:28-31]:

> Amino acid substitutions are typically of single residues; insertions usually will be on the order of about 1 to 10 amino acid residues; and deletions will range about from 1 to 30 residues. Deletions or insertions preferably are made in adjacent pairs, i.e. a deletion of 2 residues or insertion of 2 residues. Substitutions, deletions, insertions or any combination thereof may be combined to arrive at a final construct.

[37] The transmembrane region of hTF is about 23 amino acid residues long and is located at about residues 220-242 (Paper 45, fact 7, admitted in Paper 60).

[38] The cytoplasmic domain of hTF is about 21 residues long and is located at the C-terminal of the protein, residues 243-263 (Paper 45, fact 9, admitted in Paper 60).

[39] A hydropathy diagram, FIG. 5 in the 934 application [1003], shows that the hydrophobic transmembrane region does not extend to the C-terminal of the full-length hTF protein (Paper 45, fact 11, admitted in Paper 60).

[40] During prosecution before the examiner, claims directed to an hTF fragment having residues 1-219 were rejected as lacking adequate written description [1002 at 2].

[41] Genentech presented the declaration of Dr. William Konigsberg [3002] to overcome the rejection [1002 at 5].

[42] Dr. Konigberg testified [3002, ¶5]:

> [A]t the time [the 743 ancestor application] was filed, I believe that those of skill in the arts of proteins, cloning and expression, and tissue factor at that time would have understood the descriptions of deletion of the transmembrane region of tissue factor to include tissue factor proteins from which the entire C-terminal region, including the transmembrane and cytoplasmic regions, had been deleted. This is so because the deletion of the transmembrane region as described in the specification would have been viewed and understood as an indication that the extracellular domain could be used separately from both the transmembrane and the cytoplasmic region.

The relevant date for compliance with § 112(1) is the filing date of the application, not the filing date of an ancestor application. Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000). Nevertheless, we have no reason to believe that Dr. Konigsberg's declaration testimony about what one would have understood at the filing date for the 743 application ceased to be true at the filing date of the 934 application.

[43] Dr. Konigsberg proceeded to provide the basis for his opinion, identifying only two roles for the transmembrane region, the absence of which would make further connection between the extracellular and cytoplasmic domains pointless [3002, ¶5].

[44] The Board reversed the rejection in Ex parte Lawn [1002 at 2].

[45] Scripps has provided no competing expert testimony to consider.

[46] Scripps has not pointed to any description or example in the 934 application that unequivocally requires an hTF variant with both the extracellular and cytoplasmic, but not transmembrane, domains.

[47] We find Dr. Konigsberg's testimony, specifically including the bases for his opinion, to be credible.[5]

To fulfill the written description requirement, a specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997). In determining the adequacy of the written description, the Board must consider any properly admitted expert declaration, including any opinion evidence, In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996), but has broad discretion as to the weight it accords such declarations, In re American Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1368, 70 USPQ2d 1827, 1833 (Fed. Cir. 2004). It is axiomatic, however, that attorney argument is not evidence and is not entitled to evidentiary weight. Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 595, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997). On the facts of this case, we credit Dr. Konigsberg's reasoning that one skilled in the art would have understood the transmembrane deletion to imply deletion of the cytoplasmic domain as well.

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[5] The Konigsberg declaration does not identify the basis of Dr. Konigsberg's relationship with Genentech. Based on related proceedings, we have reason to believe that Dr. Konigsberg worked with Genentech in the early stages of development of the claimed invention. Given the nature of the testimony, we find the testimony credible despite this undisclosed relationship. Nevertheless, such relationships may be vital when evaluating testimony regarding written description and should be disclosed in the declaration. Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1581-82, 38 USPQ2d 1665, 1669 (Fed. Cir. 1996).

The ex parte Board decision in Lawn is not binding on Scripps, which did not participate in that appeal, and thus is not binding on the Board in the context of this proceeding. The fact that it is not binding, however, does not mean that we are barred from independently reaching the same conclusion as the Lawn panel on the record of this proceeding.

[48] We find adequate written description in the 934 specification for a 1-219 residue fragment for the reasons Dr. Konigsberg provides.

[49] We find adequate written description for the 219 residue limitation in the 934 application independent claims.

Enablement

[50] The unpatentability of the claims is not argued separately with specificity, but broadly with the argument centering on support for activity in a clotting assay (Paper 45).

[51] Three of the independent claims require clotting activity with human plasma, but none expressly require the clotting to occur in vivo (Paper 13 at 4-5).

[52] The parties broadly agree that the art of cloning deoxyribonucleic acid [DNA] and of expressing protein encoded by that DNA was an unpredictable art through early 1987 (Paper 45, fact 25, admitted with qualifications in Paper 60).

[53] The parties disagree about the state of the art on understanding coagulation through 1987 (Paper 45, facts 26-28, denied in Paper 60).

[54] Scripps argues (Paper 45 at 21) that "as late as 1991, it was not known with certainty whether the transmembrane domain of tissue factor was required for coagulation activity", citing the abstract of the Paborsky article.

[55] The Paborsky article [3011] was:

> L.R. Paborsky, I.W. Caras, K.L. Fisher & C.M. Gorman, "Lipid Association, but Not the Transmembrane Domain, Is Required for Tissue Factor Activity: Sustitution of the transmembrane domain with a phosphatidylinositol anchor", 266 J. Biol. Chem. 21911-16 (1991) (received for publication 11 June 1991).

[56] Consistent with the title of the paper, the abstract reports:

> The ability of the [phosphatidylinositol] anchor to restore activity to 219 rTF [TF(1-219)] clearly demonstrates that while the transmembrane domain is not required for TF activity, lipid association is required.

[57] In the results and discussion section of the Paborsky article [3011 at 21915, col. 1], the authors "conclude that lipid association is required for TF activity", citing the 1969 Hvatum article and two other articles from 1968 and 1970.

[58] All of the authors of the Paborsky article are identified [3011 at 21911] as being "From...Genentech, Inc."

[59] The 934 application was filed 22 May 1995.

[60] A person suffering from hemophilia B reportedly have significantly lower blood plasma levels of Factor VIIa (Paper 45, fact 29, admitted in Paper 60).

[61] The presence of Factor VIIa is critical for the hTF protein consisting of residues 1-219 [TF(1-219)] to induce coagulation (Paper 45, fact 30, admitted in Paper 60).

[62] The clotting activity of TF(1-219) in plasma depends on the plasma concentration of Factor VIIa. (Paper 45, fact 31, admitted in Paper 60).

[63] Genentech's 934 application cites a Hvatum article in describing a one-stage clotting assay (Paper 45, fact 32, admitted in Paper 60).

[64] The Hvatum article [3013] is:

M. Hvatum & H. Prydz, "Studies on Tissue Thromboplastin - Its Splitting into Two Separable Parts", 21 Thrombos. Diathes. haemorrh. 217-222 (1969).

[65] The parties dispute the significance of the reference to the Hvatum paper and what it teaches (Paper 45, facts 33-35, denied in Paper 60).

[66] They agree that the 934 application cites an in vivo assay for tissue factor activity in dogs that measures bleeding time (Paper 45, fact 36, admitted in Paper 60).

[67] The parties dispute the value of the in vivo assay disclosure (Paper 45, facts 33, 38 & 45, denied in Paper 60).

[68] They agree that the 934 application discloses a chromogenic assay that seeks to determine the ability of a substance to activate Factor X to form Factor Xa, and the Factor Xa activity is determined photometrically by measuring the degree of cleavage of a Factor Xa specific substrate that forms a chromophore upon cleavage (Paper 45, fact 39, admitted in Paper 60).

[69] They disagree about the significance of the disclosure of the chromogenic assay (Paper 45, facts 40, 42, 46 & 47, denied in Paper 60; Paper 45, fact 41, admitted with qualifications in Paper 60).

[70] The parties agree that the one-stage assay of the 934 application would not be an appropriate assay for measuring the intrinsic activity of TF(1-219) (Paper 45, facts 43, admitted in Paper 60), but otherwise disagree about the usefulness of the one-stage assay (Paper 45, facts 44, denied in Paper 60).

[71] Scripps relies on the declaration of Dr. Sriram Krishnaswamy [3003].

[72] Dr. Krishnaswamy identifies [3003, ¶ 3] 1986 as start of his experience in blood coagulation, but does not otherwise identify a relevant date for assessing his declaration testimony.

[73] Dr. Krishnaswamy's declaration [3003] is generally phrased in the present tense and thus appears to be discussing the state of the art as of the date of his declaration, 31 October 2003.

[74] Dr. Krishnaswamy declared [3003, ¶¶22 & 23] that Example 4 of the 934 application lacked information required to reproduce the results of the example.

[75] During cross examination [1012], Dr. Krishnaswamy indicated that an hTF fragment will produce clotting activity in human plasma, especially at 42:2-43:3:

> Q. With the shortened soluble tissue factor, you would get activity, though, would you not?
>
> A. Depending on how much VIIa there was, yes.
>
> Q. Now, in the hemophilic plasma, there is some VIIa, is there not?
>
> A. Absolutely.
>
> Q. So you would -- running the assay with hemophilic plasma, you would expect to get a result -- get a showing of activity?
>
> A. Once again it depends on the kind of plasma. The problem is that one of the points that I noted was that it's not clear what kind of hemophilic plasma it is.
>
> Q. What if it was human hemophilic plasma?
>
> A. Yes, absolutely; and, in fact, that's the basis for at least one paper in the field.
>
> Q. And, again you had said that the publication cited in Example 4, the Hvatum paper, that deals with human plasma, does it not?

A. Yeah, to the best of my recollection, absolutely.

[76] Dr. Krishnaswamy also characterized [3003, ¶28] the in vivo test of Example 5 as "not described with sufficient particularity to be reliably reproducible...e.g., the effect on time before the cessation of bleeding that constitutes a positive result is not specified."

[77] Example 5 purports to describe [1003 at 39:6-9] an assay of "coagulation inducing capacity in hemophilic dogs by measuring cuticle bleeding time (CBT) (Giles, A.R., et al., supra)."

[78] The Giles article [1011] is:

> A.R. Giles, S. Tinlin & R. Greenwood, "A Canine Model of Hemophilic (Factor VIII:C Deficiency) Bleeding, 60 Blood 727-30 (1982).

[79] Under cross examination [1017A at 25:12-24], Dr. Krishnaswamy agreed that the Giles assay was reproducible:

> Q Would you be able to measure the coagulation activity of 219 tissue factor in the hemophiliac A plasma of Giles?
>
> A. Bound to VIIa, yes.
>
> Q Would you be able to determine the relative activity to normal human tissue factor?
>
> A Using this assay one through 263 you mean?
>
> Q Yes.
>
> A Yes, of course.
>
> Q Is the assay used by Giles considered to be a reproducible assay?
>
> A Yes.

[80] Scripps also relies (Paper 45 at 24) on the testimony of Drs. Konigsberg [3014] and Nemerson [3016] during a European opposition proceeding.

[81] Their testimony does not address the disclosure of the 934 application.

[82] Their testimony also appears to be directed to the state of the art in 1986 and 1987 rather than 1995.

An application starts with a presumption of enablement. In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A disclosure does not enable a claimed invention if making or using the invention would require undue experimentation from one skilled in the art. Undue experimentation is determined with reference to the factors In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), enumerates. The Wands factors are, however, illustrative of the sort of factors that should be considered. Which factors are relevant depends on the facts of the case. Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

Wands factor 5 relates to the state of the prior art. Citing factor 5, Scripps argues that in vivo clotting activity was not well understood through early 1987 or even as late as 1991. At the outset, we must construe the claims as broadly as may be reasonable in view of the specification. In re Bigio, 381 F.3d 1320, 1324, 72 USPQ2d 1209, 1210-11 (Fed. Cir. 2004). None of the contested independent claims are expressly limited to in vivo clotting activity and neither party has shown that an "in vivo" limitation must be read into the claims. Consequently, we understand Scripps' in-vivo argument is more of a factor 8 (claim breadth) argument directed to the scope of

enablement, where one of the embodiments is said to lack enablement. While the disclosure must support the full scope of the claim, it need not describe how to make and use every possible variant of the claimed invention when the prior art and routine experimentation can fill gaps and even extrapolate outside the scope of disclosed embodiments. An enabling disclosure must, however, be commensurate with the scope of the claim. Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253, 70 USPQ2d 1321, 1325 (Fed. Cir. 2004).

The relevant date for determining compliance with § 112(1) is the filing date of the application with the attacked claims, not the filing date of a parent application. Reiffin, 214 F.3d at 1346, 54 USPQ2d at 1918. Since in vivo Scripps' arguments (Paper 95 at 21) are directed to proofs for dates well before the filing date of the 934 application, we accord no weight to these proofs.

Similarly, Dr. Krishnaswamy's declaration testimony appears to be substantially inconsistent with his cross examination testimony.[6] While the prior art is no substitute for an adequately enabling disclosure, the knowledge and skill in the art must be factored into understanding the adequacy of the disclosure. In this case, the disclosure points to a published protocol in the prior art that, despite his earlier testimony, Dr. Krishnaswamy admitted was reproducible. Consequently, we give very little weight to Dr. Krishnaswamy's declaration testimony regarding Example 5.

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[6] We note Scripps concerns (Paper 65 at 7) about the "1017" [sic, 1017A] transcript, but conclude that the formalities Scripps raises do not affect the import of the testimony. For instance, while the testimony does not expressly identify the "Giles" article in question, the context supports Genentech's representation and Scripps has not offered any plausible alternative explanation.

Scripps argues that Genentech's disclosure does not identify a level of activity. This argument also appears to be a factor 8 argument directed to the breadth of the claims. It is not apparent why this sort of breadth would require undue experimentation. Scripps also argues that the information in the disclosure regarding the source of hemophilic plasma in Example 4 is incomplete, citing Dr. Krishnaswamy's declaration. Dr. Krishnaswamy cross examination testimony, however, suggests that the adjustments necessary to make Example 4 work were readily apparent to him. A patent document is not intended to be a production specification. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941, 15 USPQ2d 1321, 1329 (Fed. Cir. 1990). Scripps has not pointed us to evidence of what one skilled in the art would have known on the filing date of the 934 application, but Dr. Krishnaswamy's current quibbles with the disclosure appear to be readily resolvable to Dr. Krishnaswamy.

Scripps further argues that relipidation would be necessary for any clotting activity. The Paborsky article, however, shows that the need for relipidation was known prior to the filing date of the 934 application.

Scripps has not succeeded in attacking two of the examples purporting to show activity. Since the enablement requirement can be satisfied by a single enabling embodiment, we need not decide whether Scripps has shown lack of enablement for the remaining examples.

Finally, we accord no weight on the question of enablement to the European testimony of Drs. Konigsberg and Nemerson since it does not address the relevant time or the relevant disclosure.

Scripps preliminary motion 2 is DENIED.

Scripps preliminary motion 5: attacking Genentech's accorded benefit

[83] Scripps moves (Paper 48 at 2) to remove the benefit accorded to Genentech of the filing date of the 743 application as Genentech's earliest constructive reduction to practice.

[84] Genentech was accorded (Paper 1 at 3) the benefit of the 743 application filing date--12 February 1987--for constructive reduction to practice of the subject matter of the count.

[85] The sole count is [3009]:

> 1. A composition comprising an aqueous solution of human tissue factor heavy chain protein wherein said protein is soluble and has an amino acid residue sequence represented by FIG. **1** from position 1 to position 219.

[86] Scripps maintains (Paper 48 at 9) that:

> Neither [of Genentech's involved applications] is entitled to the benefit of the filing date of [the 743 application] because the latter does not constitute a constructive reduction to practice of a single species encompassed by the subject matter of the Count as required by 37 C.F.R. § 1.637(f)(3).

[87] Scripps argues that the 743 application is not a proper constructive reduction to practice because it does not provide adequate written description, adequate enablement, and a best mode for the subject matter of the count.

The rule prescribing the content of a motion attacking benefit at the time the motion was filed was 37 C.F.R. § 1.637(g), not § 1.637(f) (which relates to a motion

seeking benefit). Although the underlying test for benefit is the same whether it is sought or attacked, we shall apply[7] § 1.637(g), which succinctly required:

> A preliminary motion to attack benefit under § 1.633(g) shall explain, as to each count, why an opponent should not be accorded the benefit of the filing date of the earlier application.

While the test for benefit in an interference is usually phrased in terms of § 112(1), it differs from that statute in at least one important regard: benefit only requires a single embodiment within the scope of the count.[8] Hunt v. Treppschuh, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975).

Enablement

[88] Scripps argues (Paper 48 at 11-12) that Genentech failed to enable the 1-219 residue protein of the count.

We start by construing the contested limitation of the count "has an amino acid residue sequence represented by FIG. 1 from position 1 to position 219." We are obliged to give the count its broadest reasonable construction and may resort to the specification only if to resolve ambiguities inherent in the claim language or obvious from arguments of counsel. DeGeorge v. Bernier, 768 F.2d 1318, 1321-22, 226 USPQ 758, 760-61 (Fed. Cir. 1985). Genentech argues that the "has" transitional phrase is

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[7] New rules came into effect after these motions were fully briefed and argued. Although the new rules do not compel a different result for any of these motions, in this decision we will continue to refer to the old rules for the sake of simplicity. See Singh v. Brake, 222 F.3d 1362, 1371, 55 USPQ2d 1673, 1679 (Fed. Cir. 2000) (explaining choice of rules when there has been a nominal change in an interference rule); accord PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1321 n.2, 56 USPQ2d 1001, 1005 n.2 (Fed. Cir. 2000) (applying old rule to patent issued under old rule, but noting result would be the same under either rule).

[8] This is because, properly understood, it is a question of anticipation under § 102(g)(1) rather than a question of entitlement to a patent under § 112.

open to the inclusion of additional elements. The transitional phrase "has" can open up a limitation, but it does not convey openness as strongly as "comprises" and, thus, does not create a presumption that the limitation is open unless the count as a whole requires an open construction. Cf. Crystal Semiconductor Corp. 246 F.3d at 1348, 57 USPQ2d at 1959 (construing a claim). Genentech has not pointed us to any aspect of the count that requires a broader reading of the amino acid sequence than simply the stated residues 1-219. Instead, Genentech relies on University of California v. Eli Lilly & Co., 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997), for the proposition that "has" necessarily opens up a limitation involving a complementary DNA. We note that the present count involves a protein, not a DNA. Moreover, Eli Lilly does not stand for the broad proposition Genentech urges. Rather, the court recounted the prosecution history of the university's patent, in which the university amended its claim to avoid a rejection based on an open construction of "having". There is no indication that the university disputed the broad reading or any discussion of why the broad reading was or was not appropriate. The court's holding did not turn on the appropriateness of the erstwhile broad reading of the claim.

Moreover, the court's discussion does not indicate that the university's claim involved a subsequence. Instead, the question was whether the university's unamended claim had been open to more than the entire protein. In the present case, the count explicitly recites, not only a subsequence, but also a property: the protein must be soluble. Solubility indicates that the transmembrane domain is substantially not present, thus reinforcing a narrow reading of the claim. Absent some persuasive

reason rooted in the language of the count itself, we decline Genentech's invitation to construe the contested limitation to include amino acid sequences with more residues than those specifically recited.

[89] Scripps argues (Paper 48 at 13) that Genentech's 743 application does not describe how to make the 1-219 residue protein.

[90] Scripps further argues (Paper 48 at 13) that the art was highly unpredictable in 1987, citing the European opposition testimony of Dr. Konigsberg [3014] and Dr. Nemerson [3016].

[91] Genentech responds (Paper 63 at 16) that there is no legal requirement to provide a working example for every aspect of the invention.

[92] Genentech also notes (Paper 63 at 17) that Scripps provides no working example for the subject matter of the count.

[93] Scripps earliest accorded benefit for the purposes of the count is more than four months after the filing date of Genentech's 743 application.

A specification need not contain a working example if the invention is otherwise disclosed in a manner that one skilled in the art would have been able to practice the invention without undue experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). While Genentech's lack of a working example weighs against a holding of enablement, it is not in itself dispositive. Moreover,Scripps' lack of a working example, while also not dispositive, indicates that Scripps had confidence in the skill in the art to provide then necessary expertise. Cf. In re Epstein, 32 F.3d 1559, 1568-69, 31 USPQ2d 1817, 1823 (Fed. Cir. 1994) (describing Board

holding that applicant's disclosure lacked same enabling disclosure said to be lacking from prior art). In this context, Genentech's lack of a working example appears to be equivocal.

We have already discussed and discounted the European opposition testimony of Drs. Konigsberg and Nemerson about the state of the art in 1987 because it does not account for the teachings of Genentech's 743 application. Scripps provided no direct expert analysis of Genentech's disclosure. Scripps has the burden of proof on the question of Genentech's lack of enabling disclosure. Scripps' indirect and equivocal proofs fall short of a preponderance of the evidence on the issue of enablement.

Written description

[94] Scripps argues (Paper 48 at 15-18) that Genentech's 743 application lacks written description for substantially the same reason it advanced in its preliminary motion 2.

[95] We find Scripps' argument unpersuasive for the same reasons offered with regard to Scripps' preliminary motion 2.

Best mode

[96] Scripps argues that Genentech failed to comply with the best-mode requirement of § 112(1) (Paper 48 at 18-19):

> Inasmuch as Genentech '743 fails to provide enablement, as well as written description, for any species within the purview of the Count, there can be no description of any best mode for preparing such species.

[97] We have already held Scripps' enablement argument to be unpersuasive.

[98] Scripps cites no precedent in which a best mode has been considered relevant to the question of constructive reduction to practice in an interference.

[99] The first case that Scripps cites in its motion (Paper 48 at 9) is Cromlish v. D.Y., 57 USPQ2d 1318 (BPAI 2000).

There are at least two fundamental errors in Scripps' argument. First, it presupposes that there is a best-mode requirement for a constructive reduction to practice. Second, it presumes that which Scripps must prove: that Genentech had a best mode in mind when it filed the '743 application.

The first question is whether there is a best-mode requirement for a constructive reduction to practice. In Cromlish, the Board denied a motion attacking benefit on the basis of a best-mode violation. The Board explained that Cromlish had failed to establish that a best mode is required for a constructive reduction to practice. While the Board did not hold that there is no best-mode requirement for constructive reduction to practice, it provided reasons for skepticism about such an argument.[9] It is disappointing that Scripps could cite Cromlish and still make the very mistake that Cromlish made. We need not resolve the question here because it is Scripps' responsibility to make out its own case in the first instance. Following Cromlish, we hold that Scripps' has not established a prima facie case for denying Genentech of its earliest constructive reduction to practice for failure to disclose a best mode.

The second question is whether Genentech had a best mode that was not disclosed. Northern Telecom, Ltd. v. Samsung Elec. Co., 215 F.3d 1281, 1286, 55 USPQ2d 1065, 1069 (Fed. Cir. 2000):

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[9] To the extent that an argument could be made that 37 C.F.R. § 1.601(g) incorporated all of the requirements of § 112(1) by referring to 35 U.S.C. 120, we note that no such argument was made and that it would be difficult to reconcile with Hunt. In future cases, the issue will be moot since the new rules expressly rely on 35 U.S.C. 102(g)(1) in defining accorded benefit and constructive reduction to practice.

> When the invention is defined, the best mode inquiry moves to determining whether a best mode of carrying out that invention was held by the inventor. If so, that best mode must be disclosed.

Scripps simply assumes that there was a best mode that was not described because, according to Scripps, no mode was described or enabled. This is the no-mode fallacy: enablement and best-mode are distinct requirements so a failure to enable does not automatically create a best-mode violation. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1330, 63 USPQ2d 1374, 1384 (Fed. Cir. 2002).

[100] We find that Scripps has failed to establish that Genentech had a best mode.

[101] We further find that Scripps has failed to establish that Genentech improperly failed to disclose any known best mode.

Scripps preliminary motion 5 is DENIED.

Scripps preliminary motion 3: judgment under § 112(1) for 989 claims

[102] Scripps moves (Paper 46 at 2) for judgment against claims 22 and 39 of Genentech's 989 application under § 112(1) for lack of adequate written description and enabling support.

[103] Genentech's 989 application claims 22 and 39 are (Paper 61, facts 2 & 3, admitted in Paper 66):

> 22. An isolated DNA molecule encoding a soluble tissue factor protein consisting of the amino acid sequence as depicted in Figure 2 from amino acid residue on to amino acid residue 219.
>
> 39. An isolated DNA molecule encoding a soluble tissue factor protein consisting of the amino acid sequence as depicted in Figure 2 from amino acid residue one to amino acid residue 219, which DNA molecule further includes a nucleic acid sequence encoding a heterologous secretory leader sequence.

[104] The relevant 263 amino acid sequence of Genentech's 989 Figure 2 is identical to amino acid residues 1-263 in Figure 1 of the count (Paper 46, fact 1, admitted in Paper 61).

[105] Genentech's 989 application identifies full-length hTF as amino acid residues 1-263 of 989 Figure 1 (Paper 46, fact 2, admitted in Paper 61).

[106] Genentech's 989 application discloses "substitutional, insertional, and deletional variants" of full-length hTF (Paper 46, fact 3, admitted in Paper 61).

[107] Genentech's 989 application characterizes one aspect of the invention as protein derivatives lacking the signal sequence and the hydrophobic portion of the protein near the C-terminal, including the transmembrane domain (Paper 46, fact 4, admitted in Paper 61).

[108] The transmembrane domain is about 23 amino acid residues located at about residues 220 to 242 of hTF (Paper 46, fact 7, admitted in Paper 61).

[109] The transmembrane domain and the cytoplasmic domain of hTF together include about the last 44 residues of full-length hTF (Paper 46, fact 9, admitted in Paper 61).

[110] The C-terminal starting from the transmembrane domain does not appear to be entirely hydrophobic in FIG. 5 of Genentech's 989 application (Paper 46, fact 10, admitted in Paper 61).

[111] Genentech's 989 application lacks working examples of DNA molecules corresponding to claims 22 and 39 (Paper 46, fact 26, admitted in Paper 61).

[112] Text of Genentech's 989 application is identical to the text of Genentech's 743 application (Paper 61, fact 1, admitted in Paper 66).

[113] Text of Genentech's 989 application is identical to the text of Genentech's 743 application (Paper 61, fact 1, admitted in Paper 66).

[114] Genentech argues that one skilled in the art would have been enabled to modify DNA to produce the 219 residue fragment of hTF (Paper 61, fact 9, denied in Paper 66).

[115] The Lawn decision was directed to a written description rejection of a protein claim [1002 at 2 (selecting claim 41 as representative) and at 4].

We have already discussed in the context of Genentech's 743 application the sufficiency of Genentech's support for the 219 residue fragment of hTF. Although neither we nor Scripps are bound by the decision in Lawn, we nevertheless reached the same result with respect to the protein claims in the 743 application. The 989 application claims subject to the present motion, however, are directed to DNA for producing the fragment, not the fragment itself. Genentech admits that the 989 application lacks working examples of the DNA in claims 22 and 39, but does not point to any other literal disclosure of such DNA. Instead, Genentech relies on the skill of the art to produce the DNA from its disclosure of the protein fragments. An applicant cannot, however, substitute the knowledge and skill in the art to produce the critical limitations that are not otherwise disclosed. Lockwood v. American Airlines, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). While one skilled in the art may have considered the claimed DNA to be obvious in view of the disclosure, that is not the test. Scripps has carried its burden of persuasion on the lack of literal disclosure, but Genentech has not carried its burden of persuasion on the presence of implicit disclosure sufficient to demonstrate possession of the claimed subject matter.

[116] We find that claims 22 and 39 of the 989 application lack adequate written description.

Scripps preliminary motion 3 is GRANTED on the basis of written description. We do not reach the question of enablement.

Scripps preliminary motion 4: judgment under § 112(2) for 743 claims

[117] Scripps moves (Paper 47 at 2) for judgment against the involved claims of Genentech's 743 application under § 112(2) for indefiniteness.

[118] Scripps only argues (Paper 47 at 8-9) the independent claims, claims 4, 20, 31, and 41, with specificity.

[119] All of the independent claims include the functional limitation that the tissue factor fragment have "activity" in a clotting assay (Paper 47, fact 3, admitted in Paper 62).

The standard for indefiniteness has been set fairly high. A claim is not indefinite merely because its scope is not ascertainable from the face of the claims; rather, it is indefinite if it is insolubly ambiguous. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003). Indefiniteness is determined from the perspective of one skilled in the art reading the claim in light of the specification. The fact that one skilled in the art might be able to infer from the specification what the applicant really meant to claim, however, does not thereby make the claim definite. Allen Eng'g v. Bartell Indus., 299 F.3d 1336, 1350, 63 USPQ2d 1769, 1776 (Fed. Cir. 2002).

Indefiniteness and enablement are distinct requirements. A claim might not be enabled and yet still be definite. Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692, 57 USPQ2d 1293, 1297 (Fed. Cir. 2001). Indeed, if the claim is

enabled, the fact that some experimentation may be necessary to determine the scope of the claims does not render the claims indefinite. Exxon Res. & Eng'g Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1279 (Fed. Cir. 2001). A claim of "undue breadth" presents an issue under § 112(1), not § 112(2). In re Hyatt, 708 F.2d 712, 714, 218 USPQ 195, 197 (Fed. Cir. 1983).

Scripps' arguments regarding clotting activity in the 743 application claims are substantially the same as its arguments in Scripps preliminary motion 2 regarding enablement. We rejected those arguments in the context of enablement. The argument is, if anything, less persuasive in the context of indefiniteness.

[120] Scripps further argues (Paper 47 at 13) that "nucleotide molecule" is indefinite in a context that requires a "polynucleotide".

We agree that the claims must be construed to require a polynucleotide, but conclude that one skilled in the art would not find "nucleotide molecule" used in a context that requires a polynucleotide to present an insoluble ambiguity, particularly in light of the underlying specification.

[121] Scripps further argues (Paper 47 at 13) that the claims are open to any amino acid sequence as long as it is expressed from a polynucleotide that can also encode the recited amino acid sequence.

[122] Scripps does not identify the language that renders the claims open in this manner.

[123] Taking claim 20 as an example (Paper 13 at 4), the claimed subject matter must be:

> 20. A soluble isolated tissue factor fragment expressed from a nucleotide molecule encoding tissue factor in a recombinant non-human host cell, the tissue factor having the amino acid sequence shown in

[126] Genentech moves to add claims to its 743 application in the event that any of Scripps preliminary motions 1-4 are granted.

Only Scripps preliminary motion 3 has been granted, but it relates to claims 22 and 39 of the 989 application. Consequently, the relevance of Genentech's contingent motions to this proceeding is not apparent. Genentech's contingent motions 2 and 3 are DISMISSED as moot.

DECISION

DECIDED that Scripps preliminary motion 1 be DENIED;

FURTHER DECIDED that Scripps preliminary motion 2 be DENIED;

FURTHER DECIDED that Scripps preliminary motion 3 be GRANTED;

FURTHER DECIDED that Scripps preliminary motion 4 be DENIED;

FURTHER DECIDED that Scripps preliminary motion 5 be DENIED;

FURTHER DECIDED that Genentech preliminary motion 2 be DISMISSED as moot;

FURTHER DECIDED that Genentech preliminary motion 3 be DISMISSED as moot; and

FURTHER DECIDED that a copy of this decision be entered in the administrative records of Genentech's 08/437,989 and 08/444,934 applications and Scripps' 5,622,931 patent.

cc (via electronic mail):

For Scripps Research Institute: **Talivaldis Cepuritis** and **Dolores T. Kenney**, OLSON & HIERL, LTD. of Chicago, Illinois.

For Genentech, Inc.: **R. Danny Huntington** and **Donna M. Meuth**, BURNS, DOANE, SWECKER & MATHIS L.L.P. of Alexandria, Virginia.

Notice: Agreements and understandings regarding the termination of an interference are subject to filing requirements under 35 U.S.C. 135(c).

Townes, Yolunda

From: Townes, Yolunda on behalf of Interference Trial Section

Sent: Monday, February 28, 2005 8:51 AM

To: 'Cepuritis, Talivaldis (OLSON & HIERL)'; 'Crane, Sharon (BURNS DOANE)'; 'Huntington, Danny (BURNS DOANE)'; 'Kenney, Dolores (OLSON & HIERL)'

Subject: Interference #105135_083 (RT) - Decision-Bd.R. 125(a)-Preliminary Motions